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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|---------------------------|-----------------------------|------------------|
| 10/702,688 | 11/06/2003 | Stephan Anthony Billstein | 4-31253B/C1 | 8997 |
| 1095 7590 04/09/2007 NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080 | | | EXAMINER HUI, SAN MING R | |
| | | | ART UNIT 1617 | PAPER NUMBER |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS | | 04/09/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/702,688

Applicant(s)

BILLSTEIN ET AL.

Examiner

San-ming Hui

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 55-60 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 55-60 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/15/04, 11/6/03</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

This is a continuation of US Serial 09/722,784, filed 11/27/2000.

Claims 55-60 are pending for examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 55-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giger et al. (US Patent 5,510,353), Langtry et al. (Drugs, 1998; 56(30):447-486) and Rasmussen et al., Scand J Gastroenterol, 1999;7:671-675.

Giger et al. teaches tegaserod as one of the exemplified aminoguanidine compounds useful for treating disorders associated with GI motility such as gastro-oesophageal reflux disease (GORD) (See col. 14, Table I, example 13; also col. 20, line 65 to col. 21, line 2; also claims 9 and 10). Giger et al. especially teaches that the aminoguanidine compounds including tegaserod as useful normalize gastric emptying (See col. 20, line 65-67 bridging col. 21, lines 1-5 especially). Giger et al. also teaches that aminoguanidine compounds wherein R_1 is H, A is $-\text{CH}=\text{}$, Z is $-\text{CH}=\text{}$ and R_5 is C_{1-6} alkoxy is useful to treat motility disorders (See col. 24, line 65 to col. 25, line 2). Examiner notes that tegaserod is compound of formula I when R_1 is H, A is $-\text{CH}=\text{}$, Z is $-\text{CH}=\text{}$, and R_5 is C_1 alkoxy (See col. 14, Table I, example 13).

Langtry et al. teaches omeprazole is useful in treating GORD (See the abstract, page 463, col. 1, third paragraph to page 469 col. 2, first paragraph).

Rasmussen et al. teaches omeprazole's ability to delay gastric emptying (See for example the abstract).

The references do not expressly teach a method of regulating gastrointestinal motility with both tegaserod and omeprazole together.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to concomitantly employ both tegaserod and omeprazole together in a method of regulating gastrointestinal motility and treating the GORD.

Art Unit: 1617

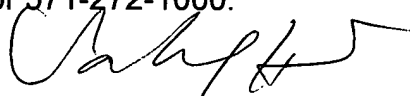
One of ordinary skill in the art would have been motivated to c concomitantly employ both tegaserod and omeprazole together in a method of regulating gastrointestinal motility and treating the GORD. Both tegaserod and omeprazole are known to be useful for treating GORD and regulate GI motility individually. It would flows logically to concomitantly employ tegaserod and omeprazole together into a method useful for the very same purpose, i.e., regulating GI motility and treating GORD, absent evidence to the contrary, at least additive effect is expected (See *In re Kerkhoven* 205 USPQ 1069).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1617

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



San-ming Hui
Primary Examiner
Art Unit 1617